Situation Analysis: Introducing Pharmaceutical Product Registration Policy in Angola

July 2016

USAID
FROM THE AMERICAN PEOPLE

SIAPS
Systems for Improved Access to Pharmaceuticals and Services

Situation Analysis: Introducing Pharmaceutical Product Registration Policy in Angola

EunMi Kim

July 2016

This report is made possible by the generous support of the American people through the US Agency for International Development (USAID), under the terms of cooperative agreement number AID-OAA-A-11-00021. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to ensure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS results areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

Recommended Citation

This report may be reproduced if credit is given to SIAPS. Please use the following citation.

Kim, EunMi. 2016. *Situation Analysis: Introducing Pharmaceutical Product Registration Policy in Angola.* Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

Key Words

Medicine product registration, pharmaceutical product registration, product marketing authorization

Systems for Improved Access to Pharmaceuticals and Services
Pharmaceutical & Health Technologies Group
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703.524.6575
Fax: 703.524.7898
E-mail: siaps@msh.org
Website: www.siapsprogram.org

CONTENTS

ACRONYMS AND ABBREVIATIONS

ANVISA	Agência Nacional de Vigilância Sanitária
DNME	Department for National Medicines and Equipment
IGS	Inspecção-Geral da Saúde
MINSA	Ministry of Health (Ministério da Saúde)
NMRA	national medicines regulatory authority
NQL	national quality laboratory
PMS	postmarketing surveillance
PSUR	periodic safety update report
SADC	Southern African Development Community
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SOP	standard operating procedure
WHO	World Health Organization

ACKNOWLEDGMENTS

I would like to express my deep gratitude to the National Directorate of Medicines and Equipment (Direcção Nacional de Medicamentos e Equipamentos; DNME) of the Ministry of Health (Ministério da Saúde; MINSA) for its commitment and strong leadership to establish a medicine product regulatory system in Angola. In particular, I would like to acknowledge Dr. Boaventura Moura, Director General of the DNME; Dr. Pombal Mayembe, former head of National Department of Medicines and Sanitary Products of the DNME; and the entire staff of the registration unit for their support and time to conduct brief situation analyses and for sharing their valuable opinions.

I am also deeply appreciative of the support provided by the staff at the Systems for Improved Access to Pharmaceuticals and Services (SIAPS)/Angola Program, including Mr. Patrick Gaparayi, SIAPS Country Program Director, and Mr. Lubaki João for their support in arranging meetings with stakeholders and collecting relevant information for conducting situation analyses in country. Last but not least, thanks to Diadié Maïga for technical review and inputs, and to Wonder Goredema and Lubaki João for coordinating editorial review, finalization and dissemination of the report.

EXECUTIVE SUMMARY

Background

The DNME of the MINSA recognizes the importance of regulating pharmaceutical products and wants to introduce a new policy to mandate product registration to better control the safety, quality, and efficacy of pharmaceutical products. The National Department of Medicine and Health Products of the DNME is the responsible unit for managing pharmaceutical product registration. However, the unit has been challenged by a lack of staff and budget when preparing to implement this new policy.

The DNME has been preparing to implement a new policy that will switch from importer-based regulations to product-based regulations. However, has been challenging to build a comprehensive database on the importation and distribution of pharmaceutical products that could be used to understand the quantities and types of medicines that need to be registered.

In 2012, the US Agency for International Development-funded SIAPS Program conducted a comprehensive assessment of the current regulatory system in Angola and the DNME's capacity to strengthen that system[1]. As a follow-up, in April 2015 and 2016, SIAPS was invited by the DNME to provide technical assistance to prepare a new policy that would mandate product registration by assessing the current situation and developing implementation strategies for the new policy.

Methodology

The SIAPS team briefly assessed both the current status and the preparation activities through key informant interviews with DNME staff and provided onsite training on how to prepare for policy implementation.

The specific areas of the assessment included:

- Legal framework: Presence of relevant laws and regulations
- Regulatory tools: Readiness of relevant regulatory tools, such as guidelines, standard operating procedures (SOPs), and official application forms
- Product list: Availability of the product information for marketed pharmaceutical products
- Human resources: Capacity to train technical staff and the availability of human resources

[1] Thumm M, Gaparayi P, Goredema W, Tjipura D. *Assessment of the Medicines Regulatory System in Angola: Report.* Management Sciences for Health, Arlington, VA: 2013.

- Strategic plan: Presence of short- and long-term strategies to strengthen the regulatory system with a focus on implementing a new medicine registration policy

- National Quality Laboratory (NQL): Capacity to conduct quality testing of products for product marketing authorizations

Findings

All imported medicines in Angola are currently regulated by registering importers through the DNME. All individual permits of importation of pharmaceutical products are regulated by the DNME in collaboration with the Custom Clearance Office, the Ministry of Finance, and other responsible government agencies. The DNME is responsible for reviewing the status of registered importers and their lists of products, while the Custom Clearance Office is responsible for conducting visual inspections and filing applications.

The readiness to implement a pharmaceutical product registration policy in Angola is challenged by the lack of infrastructure and technical capacity.

Legal Framework

Although a comprehensive national health policy was adopted in 2010, a more detailed law mandating medicine registration has not yet been approved. A law mandating product registration prior to importation and distribution to the market was submitted to the National Assembly in 2011, but the bill has not been rectified to date.

Regulatory Tools

The DNME has identified and prepared some regulatory tools on product registration, including new product registration guidelines, product marketing authorization application forms, and SOPs for the product registration review process. DNME staff have been attending trainings provided by the World Health Organization (WHO) as well as other national medicines regulatory authorities (NMRAs) to learn how to prepare pharmaceutical product registration. However, due to the high turnover of technical staff in the registration unit, knowledge of the relevant regulatory tools has not been properly transferred. In addition, most regulatory tools need to be updated so that DNME can adopt regulatory guidelines on medicine registration that are harmonized with those adopted by Southern African Development Community (SADC) countries.

Product List

A repository of imported medicine data, including the list and detailed product information, that would aid in understanding the current pharmaceutical market is not available. The data, which have been collected by department government bodies, are fragmented and are not completely suitable for medicine registration data management purposes.

Human Resources

Due to both the high turnover of technical staff in the registration unit and recent budget cuts, the department is understaffed to prepare for the implementation of the pharmaceutical product registration policy. The institutional capacity to train technical staff to review technical documents for product marketing authorization is lacking.

Strategic Plan

Due to the long delay in getting the law approved, the DNME has not been able to develop a strategic plan on how to implement the new pharmaceutical product registration policy, although it has been reviewing different approaches by visiting other NMRAs in neighboring countries.

National Quality Laboratory

The DNME does not have its own functional NQL to conduct quality testing of pharmaceutical products for product marketing authorizations or postmarketing surveillance (PMS). It has been sending product samples to the laboratories of other NMRAs, such as Infarmed in Portugal, or to the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária; ANVISA) in Brazil.

Recommendations

Collaboration with other responsible government bodies is strongly recommended to redefine and change stakeholder roles and responsibilities. A working group of stakeholders is needed to develop a new importation process. Members should develop a new importation process map, including the roles and responsibilities of each stakeholder. To streamline the process, an online importation approval processing tool can be used.

A stepwise approach to introducing a new policy to mandate product registration and prevent any issues with supplying necessary medicines to the public has also been recommended. This approach will enable importers and suppliers of medicines to prepare technical dossiers to submit for product registration. The DNME can issue provisional product marketing authorizations after the database of product lists is built. During the grace period, the DNME should be able to provide proper guidance to the industry to prepare for new product registration applications.

- Step 1: Build the data inventory of product lists by collecting data on pharmaceutical products imported into and manufactured in the country
- Step 2: Issue provisional (temporary) product marketing authorizations
- Step 3: Introduce premarket evaluations and product marketing authorizations

To prepare to implement the new policy, the DNME also needs to strengthen the regulatory system, including the medicine registration processes. Without this, it will be challenging to enforce newly adopted policies and regulations.

Legal Framework

MINSA and the DNME should organize a media campaign to increase public awareness of the importance of the new policy, which will improve the safety, quality, and efficacy of medicines in Angola. There have been many safety cases reported in the country that have caused patient injuries or deaths. To pass the bill, the government also should take serious actions to improve governance and transparency in mandating pharmaceutical product registration.

Regulatory Tools

Although the DNME has prepared regulatory tools in the past, most guidelines and other regulatory tools need to be updated so that the DNME can adopt regulatory guidelines on medicine registration that are harmonized with those adopted by SADC countries. More detailed guidance documents are needed to guide the industry and avoid confusion among stakeholders.

Product List

The DNME should be able to create a complete inventory list of medicines marketed in the country through collaboration with other government agencies that have data on imported medicines. The DNME also needs to collaborate with industry, wholesalers, and other distribution channels to obtain the history of importation and medicine supply. The Inspecção-Geral da Saúde (IGS) also should collaborate with the registration unit to obtain inspection data of the premises to collect information on supplied medicines. A data collection form should be developed by the DNME to build a searchable database of medicine lists. Searchable data should include product name (both generic and brand names), active ingredients and quantities, dosage form, route of administration, manufacturer's and license holder's names and full addresses, name of the representatives of a premise (manufacturer or importer), pharmaceutical or/and therapeutic classifications, indications, package sizes and prices, and other necessary information.

Human Resources

The DNME should develop a long-term strategic plan on human resource development to enable effective medicine registration. The plan should include recruiting appropriate technical staff, qualifications for job criteria, and training and retention.

Strategic Plan

The DNME needs to develop both short- and long-term strategic plans that include strategies for strengthening regulatory systems to enforce new polices related to medicine registration. The new policy includes premarket product marketing authorization and mandates other regulatory compliance, such as labeling, variations of registered products, periodic safety update reports (PSURs), PMS, and inspections. Therefore, the strategic plan should include other regulatory aspects to ensure the enforcement of product registration.

National Quality Laboratory

Building an NQL can be challenging in terms of both financing and technical capacity. The DNME needs to ensure that proper quality tests for premarket product registration review are conducted. It can continue to utilize current arrangements, such as Infarmed in Portugal or ANVISA in Brazil. However, because the number of sample tests is expected to increase dramatically, the DNME needs to make arrangements with local laboratories or foreign agencies until it can build a functional NQL.

INTRODUCTION

The DNME, which is under MINSA, is responsible for ensuring the quality, efficacy, and safety of medicines and other health products in Angola. Most medicines sold and used in Angola are imported, and the DNME has been controlling the importation of products by licensing importers and conducting inspections. Only licensed importers and distributors are allowed to import and distribute pharmaceutical products in Angola. The importation of pharmaceutical products is controlled by licensing importers and inspecting licensed importers through the IGS under the Departamento de Inspecção Farmacêutica (Department of Pharmaceutical Inspection) and the registration unit of the National Department of Medicine and Health Products of the DNME. Control of the importation process has been coordinated in collaboration with other government bodies, such as Ministry of Finance and customs offices.

Medicine product registration policies have been widely used in other NMRAs to effectively control the quality, safety, and efficacy of pharmaceutical products. In addition to licensing manufacturers and importers, each product needs to be registered after a comprehensive technical review of its safety, quality, and efficacy. Product marketing authorizations must be renewed and can be suspended or cancelled based on regulatory decisions even after the product is registered. In this way, NMRAs can better monitor the postmarket safety and usage of medicines.

To better control medicine supply and use, the government of Angola has decided to introduce a medicine product registration policy. However, the DNME of MINSA has faced challenges in implementing the new medicine product registration policy due to a delay of the ratification of the relevant law that would establish the legal framework to introduce the policy[2]. The DNME currently operates as a national directorate within MINSA. However, if the DNME can become an autonomous body, as described in the Health Development Plan's Program for Pharmaceutical Development, it is expected to serve as the NMRA.

[2] Thumm M, Gaparayi P, Goredema W, Tjipura D. *Assessment of the Medicines Regulatory System in Angola: Report.* Management Sciences for Health, Arlington, VA: 2013.

BACKGROUND

The government of Angola and MINSA recognize the importance of regulating pharmaceutical products and are working to introduce a new policy mandating product registration that will better control the safety, quality, and efficacy of pharmaceutical products. The National Department of Medicine and Health Products of the DNME is responsible for managing pharmaceutical product registration. However, the unit has been challenged by the lack of staff and budget when preparing to implement the new policy.

The DNME has been preparing to implement a new policy that will switch from importer-based regulations to product-based regulations. However, has been challenging to build a comprehensive database on the importation and distribution of pharmaceutical products that could be used to understand the quantities and types of medicines that need to be registered.

In 2012, SIAPS conducted a comprehensive assessment of the current regulatory system in Angola and DNME's capacity to provide technical support to strengthen the regulatory system. As a follow-up, in April 2015 and 2016, SIAPS was invited by the DNME to provide technical assistance to prepare a new policy that would mandate product registration by assessing the current situation and developing implementation strategies for the new policy. This report was written to assist the DNME in preparing to implement premarket pharmaceutical product marketing authorization and related enforcement policies.

FINDINGS

All imported medicines in Angola are currently regulated by registering importers through the DNME. All individual permits of importation of pharmaceutical products are regulated by the DNME in collaboration with the Custom Clearance Office, the Ministry of Finance, and other responsible government agencies. The DNME is responsible for reviewing the status of registered importers and their lists of products, while the Custom Clearance Office is responsible for conducting visual inspections and filing applications.

The readiness to implement a pharmaceutical product registration policy in Angola is challenged by the lack of infrastructure and technical capacity.

Legal Framework

Although a comprehensive national health policy was adopted in 2010, a more detailed law mandating medicine registration has not yet been approved. A law mandating product registration prior to importation and distribution to the market was submitted to the National Assembly in 2011, but the bill has not been rectified to date.

Regulatory Tools

The DNME has identified and prepared some regulatory tools on product registration, including new product registration guidelines, product marketing authorization application forms, and SOPs for the product registration review process. DNME staff have been attending trainings provided by WHO as well as other NMRAs to learn how to prepare pharmaceutical product registration. However, due to the high turnover of technical staff in the registration unit, knowledge of the relevant regulatory tools has not been properly transferred. In addition, most regulatory tools need to be updated so that DNME can adopt regulatory guidelines on medicine registration that are harmonized with those adopted by SADC countries.

Product List

A repository of imported medicine data, including the list and detailed product information, that would aid in understanding the current pharmaceutical market is not available. The data, which have been collected by department government bodies, are fragmented and are not completely suitable for medicine registration data management purposes.

Human Resources

Due to both the high turnover of technical staff in the registration unit and recent budget cuts, the department is understaffed to prepare for the implementation of the pharmaceutical product

registration policy. The institutional capacity to train technical staff to review technical documents for product marketing authorization is lacking.

The 2012 comprehensive assessment identified four staff within the registration unit, including two pharmacists, one pharmacy technician, and one administrative support person.

Strategic Plan

Due to the long delay in getting the law approved, the DNME has not been able to develop a strategic plan on how to implement the new pharmaceutical product registration policy, although it has been reviewing different approaches by visiting other NMRAs in neighboring countries.

National Quality Laboratory

The DNME does not have its own functional NQL to conduct quality testing of pharmaceutical products for product marketing authorizations or PMS. It has been sending product samples to the laboratories of other NMRAs, such as Infarmed in Portugal or ANVISA in Brazil.

RECOMMENDATIONS

To prepare to implement a new medicine registration policy, the DNME of MINSA needs to develop a strategic plan with detailed implementation plans. Once a bill is passed to establish the basic legal framework, the DNME can start taking steps to implement a lower-level legal framework that includes more detailed regulations and regulatory tools, such as relevant guidelines, SOPs, and official forms.

The DNME should perform an inventory of products which are being marketed. Once the data inventory is built, the DNME can issue provisional marketing authorizations for importers who wish to continue importing products. Importers can apply for provisional marketing authorization during the grace period by submitting product information, including the product profile, manufacturer information, the certificate of analysis, labels, insert papers, pro forma invoices, and other relevant documents.

During the grace period, the DNME can implement premarket evaluations for product registration for a product that has not been marketed in the country. To set up the premarket evaluation process, the DNME needs to finalize and adopt new product registration guidelines, train internal staff, and distribute the guidelines to applicants who are preparing product applications. Review guidelines and checklists should be also available for personnel who are reviewing technical dossiers and making decisions based on scientific evidence and approved guidelines. The DNME can set up multiple teams comprising technical reviewers to review different types of medicines, including biological products, vaccines, and chemical products. It can also establish technical committees in line with SADC recommendations and guidelines. Different review guidelines that are based on benchmarking guidelines used in other NMRAs need to be developed.

To implement the new medicine registration policy, the medicine importation process needs to be reshaped. The process map should be refined, and guidelines should be developed in collaboration with relevant government bodies. A taskforce team comprising representatives from each government body and related agencies should define the new importation process and incorporate changes related to medicine registration. An online system that can manage the importation process can reduce the time needed to collect product registration information and improve the transparency of the import permit process.

The DNME also plans to introduce a system to manage regulatory data, including product registration data, safety data, inspection reports, quality assurance tests, and other regulatory data. Before building the data management system, it is important to develop clear objectives and a scope of work by conducting a careful assessment of the current infrastructure and needs. A complete list of products marketed in the country can be the foundation on which to build a more comprehensive regulatory data management system. Therefore, it is important to collect usable data in a carefully designed template that can be used to digitize data rather than collecting narrative data in an inconsistent manner.

The government of Angola has shown strong support for introducing a new policy to mandate product registration to market pharmaceutical products in the country. However, adequate resources and budget allocations are lacking. Without careful preparation, the introduction of the new policy will be prolonged, and it may cause confusion and resistance within industry. Therefore, it is strongly recommended to support the DNME and other regulatory agencies, including the NQL, to build both institutional and individual capacity in preparation for these changes.

NEXT STEPS

Implementation of Medicine Registration Policy

Implementation of the pharmaceutical product registration policy is both critical and challenging due to the lack of human and financial resources. We recommend taking a stepwise approach to introducing a new policy that will mandate product registration to prevent any issues with supplying necessary medicines to the public. By using this approach, importers and suppliers of medicines can also prepare technical dossiers to submit for product registration. The DNME can issue provisional product marketing authorizations after the database of product lists is built. During the grace period, the DNME should be able to provide proper guidance for the industry to prepare for new product registration applications. The following steps can help minimize the risks associated with the new medicine registration policy. Each step could take two to three years to implement depending on the availability of necessary technical staff, collaboration among stakeholders, and the number of unregulated medicines on the market.

Step 1: Database of Medicines on the Market (up to two years)

1. The DNME and the intergovernmental taskforce team should collect data on pharmaceutical products that imported and those that are manufactured in the country.

2. The DNME should be able to verify the authentication of the collected data by cross-checking the approved medicines list and the history of imported medicines.

3. The DNME should build a comprehensive database of medicines that includes searchable information (e.g., brand name; generic name; active ingredients and quantity; dosage form; route of administration; names and full addresses of the manufacturers, importers, distributors, and license holders; contact information for representatives; pharmaceutical classification; and labeling information).

4. The DNME should finalize the official medicine registration guidelines and application forms for provisional marketing authorization. The guidelines should include the data requirements to apply for provisional marketing authorization. These requirements should include at a minimum proof of the product's importation history, existing labeling information, marketing authorization from the country of origin or the certificate of pharmaceutical product issued by the NMRA, the manufacturing license/certificate from the NMRA, the good manufacturing certificate, and other technical documents that will confirm the product's safety, quality, and efficacy.

Step 2: Provisional Marketing Authorization (up to three years)

1. The DNME should issue provisional (temporary) product marketing authorizations to ensure the supply of medicines during the grace period.

2. The DNME should consider taking a stepwise approach in issuing provisional marketing

authorizations. For example, it can select specific therapeutic groups when mandating and issuing provisional marketing authorizations in the first year and then move to other categories of medicines in subsequent years rather than implementing the policy for all medicines at once.

3. The DNME should also be ready to provide guidance and training for industry to explain the policy and maximize compliance.

4. DNME technical staff should be trained to review technical dossiers in collaboration with WHO, national regulatory authorities, and other regulatory training institutions. The DNME can also consider establishing technical review committees comprising technical experts in different areas, including pharmacists, medical doctors with different specialties, and toxicologists. Committee guidelines should be developed to prevent any conflicts of interest.

5. The DNME should refer to the SADC recommendations and guidelines to ensure proper implementation and integration of the common standards.

6. An online product registration system that can automate the application and review process should be considered. This will help the DNME reduce the burden of managing a large number of applications manually.

Step 3: Premarket Product Marketing Authorization (up to three years)

1. The DNME should introduce full premarket evaluations and marketing authorizations of pharmaceutical products.

2. During this period, the DNME can switch from provisional marketing product authorizations to fully adopted product marketing authorizations if the license holder of the provisional marketing product authorization can meet the DNME's requirements by submitting data and samples of products for testing.

3. The online product registration system should be updated to reflect changes in data requirements from adopting SADC guidelines and other international standards, such as common technical document dossier requirements.

Regulatory System Strengthening

When preparing to implement the new policy, the DNME also needs to strengthen the regulatory system, including the medicine registration process. Without this, enforcing the newly adopted policies and regulations will be challenging.

Legal Framework and Regulatory Tools

- Laws and regulations: The DNME needs to establish a firm regulatory framework to mandate the medicine registration policy and to become the sole enforcement body for the policy.

Once the law is passed, relevant regulations need to be developed to define the roles and responsibilities for mandating enforcement activities.

- SADC guidelines: The DNME has been participating in SADC working groups and is ready to implement the developed guidelines on medicine registration. It should continue to learn from other member countries when implementing these guidelines.

- Regulatory tools: Although the DNME has prepared regulatory tools in the past, most guidelines and other regulatory tools need to be updated because it wants to adopt regulatory guidelines on medicine registration that are harmonized with those adopted by SADC countries. More detailed guidance documents are needed to avoid confusion among stakeholders.

Imported Medicine Database and Online Registration System

- Database: The DNME should create a complete inventory list of medicines marketed in the country by collaborating with other government agencies that have data on imported medicines. The DNME also needs to collaborate with industry, importers, and other distribution channels to collect the importation and supply history. The IGS also should collaborate with the registration unit to obtain data on supplied medicines from inspections of premises. A data collection form should be developed by the DNME to build a searchable database of medicines lists.

- Online regulatory data management system: The DNME needs to strengthen the regulatory data management system by establishing a central database to ensure data protection and limit access. The product information related to the rational and correct use of medicines should be readily available to the public and health care professionals.

- Renewal and variations of registered pharmaceutical products: Once the online product registration system is established, the DNME can add functions such as renewals and variations of registered pharmaceutical products.

Integrated Medicine Regulatory Management System

- PMS: Related regulatory functions need to be strengthened, including PMS. The DNME should collect samples from health care facilities and markets to ensure the authenticity and quality of the products. Product safety should be monitored through a pharmacovigilance system.

- Online regulatory data management system: Other regulatory functions, such as importation, licensing of premises, inspections, and PMS, can be integrated into the comprehensive regulatory data management system. In this way, technical staff can conduct their regulatory work in a more systematic and transparent manners.

Institutional Capacity Building

- Human resources development: The DNME should develop a long-term strategic plan for

human resource development to enable effective medicine registration. The plan should include recruiting appropriate technical staff, qualifications for job criteria, and training and retention.

- Strategic plan: The DNME and MINSA need to develop short- and long-term strategic plans that include strategies for strengthening the regulatory system to enforce new medicine registration polices. The new policy should include premarket evaluation marketing authorization and should mandate other regulatory compliance, such as labeling, variations of registered products, PSURs, PMS, and inspections. Therefore, the strategic plan should include other regulatory aspects to ensure the enforcement of product registration.

National Quality Laboratory

- Building an NQL can be challenging in terms of both financing and technical capacity. The DNME needs to ensure that proper quality tests for premarket product registration review are conducted. It can continue to utilize current arrangements, such as Infarmed in Portugal or ANVISA in Brazil. As the quantity of sample tests is expected to increase dramatically, the DNME needs to arrange for the use of local laboratories or foreign agencies until it can build a functional NQL.

- By collaborating with other NMRAs, the DNME can also improve the efficiency of conducting inspections of manufacturing sites and sample tests of medicines that have been approved by other stringent NMRAs. The DNME should establish a network with other NMRAs to learn about more advanced medicine registration management systems and strengthen the institutional capacity through cost and time savings.